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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/806,989	05/29/01	LAUTT	W 2495.00071

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1614	5

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/806,989	Applicant(s) LAUTT et al.
	Examiner First Last	Art Unit 1234

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claims 1-8 are presented for prosecution on the merits.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

2. Claim 1 is objected to because of the following informalities: claim 1 is objected to because it is essentially incomplete in that it lacks a "host" or "patient" to whom the compound is administered. It is respectfully requested that Applicant amend the claims accordingly. Appropriate correction is required.

3. Claim 8 provides for the use of a compound which stimulates nitric oxide production in the liver, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For purposes of this office action, claim 8 will be treated as a method of treating similar to claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Petrie et al.(cited in parent PCT application).

Petrie et al., for purposes of studying insulin sensitivity and nitric oxide production, teach a method of administering pharmaceutical compositions of sodium nitroprusside to an individual by means of injection. Please see page 1332, col. 1, first paragraph before Statistical Evaluation.

The claims are anticipated by Petrie et al. because Petrie discloses administration of an identical compound (see Applicant's specification page 8, second full paragraph) to a host using the claimed method steps. Accordingly an increase in insulin sensitivity is inherent.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al., 6,165,975.

Adams et al. teach pharmaceutical compositions comprising effective amounts of either sodium nitroprusside, 3-morpholinosydnonimine, molsidomine, S-nitroso-N-acetyl penicillamine (SNAP) and a pharmaceutically acceptable carrier. Please see abstract; col. 7, lines 33-47; col. 15, lines 1-67.

7. Claims 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Papandreou et al., 6,171,232.

Papandreou et al. teach that sodium nitroprusside is a generally approved nitric oxide donor pharmaceutical. Furthermore, other known nitric oxide pharmaceuticals include sodium nitrite and the Sydnonimines. Please see col. 6, lines 45-55.

8. Claims 5, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Salzman et al., 5,958,427.

Salzman et al. teach pharmaceutical compositions comprising effective amounts of nitric oxide donor compounds. Please see the abstract; col. 2-6.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 2, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrie et al., supra in view of Lautt et al., 5,561,165.

Petrie et al. as applied above.

Petrie et al. do not specifically disclose administering sodium nitroprusside to the individual by oral administration or by infusion into the portal vein; however, the Examiner refers to Lautt et al. (Note common inventive entity) which discloses a method for treating insulin resistance, wherein the method comprises administering an effective amount of cholinergic agonists. Lautt et al teach that the agonists may be administered orally or, as shown in the Examples, by infusion into the portal vein. Please see col. 5, lines 31-35; col. 6, lines 49-50 and lines 65-66.

It would have been obvious to one of ordinary skill in the art to modify the method of Petrie et al. to include oral administration or administration via the portal vein because Lautt et al. suggest that these are preferred modes of administration and further because Lautt et al. show that acetylcholine administered via the portal vein reversed insulin resistance in rats (see Ex. 4). Therefore, such a modification would have been motivated by the reasoned expectation of successfully and effectively administering sodium

nitroprusside to the individual in Petrie et al. Finally, mode of administration is an art-recognized, result-effective variable and it would have been obvious to one of ordinary skill in the art to modify it in the method of Petrie et al.

Conclusion

Claims 1-8 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

Aug. 25, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600